# 510(K) SUMMARY

APR 3 0 2010

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92(c).

The assigned 510(k) number is:

### 1. Submitter:

Shenzhen Mindray Bio-medical Electronics Co., LTD Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China

Tel: +86 755 2658 2551 Fax: +86 755 2658 2680

### Contact Person:

Meng Xianjun Shenzhen Mindray Bio-medical Electronics Co., LTD Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China

Date Prepared: Jan. 08, 2010

2. <u>Device Name</u>: DC-7 Diagnostic Ultrasound System

### Classification

Regulatory Class: II Review Category: Tier II

21 CFR 892.1550 Ultrasonic Pulsed Doppler Imaging System (90-IYN)

21 CFR 892.1560 Ultrasonic Pulsed Echo Imaging System (90-IYO)

21 CFR 892.1570 Diagnostic Ultrasound Transducer (90-ITX)

### 3. Marketed Device:

DC-7 Diagnostic Ultrasound System is substantially equivalent to the following devices: Mindray DC-7 (K#092691), Mindray DC-3 (K#091941), GE Logiq P5 (K#060993), GE Voluson 730 (K#041688).

Compared to the original submission (K#092691), the technological characteristics are almost identical in this submission except for the new features and indications such as

new probes, software functions, new algorithm and etc.

The only unique feature found on the DC-7 compared to the predicate devices is the calculation of the ABI(ankle-brachial index), this feature does not affect the safety or effectiveness of the device.

### 4. Device Description:

The DC-7 Diagnostic Ultrasound System is a general purpose, portable, software controlled, ultrasound diagnostic system. Its function is to acquire and display ultrasound images in B-mode, M-mode, Color mode, Color M mode, PW mode, CW mode, Power/DirPower mode, TDI mode or the combined mode (i.e. B/M Mode). This system is a Track 3 device that employs an array of probes that include linear array probe, convex array probe, phased array probe and volume probe with a frequency range of approximately 1.8 MHz to 12.0 MHz.

### 5. Intended Use:

The DC-7 Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in abdominal, cardiac, small organ (breast, testes, thyroid, etc.), peripheral vascular, fetal, transrectal, transvaginal, pediatric, neonatal cephalic, musculoskeletal(conventional and superficial), intraoperative and transcranial exams.

### 6. Safety Considerations:

The DC-7 Diagnostic Ultrasound System had been tested as Track 3 Device per the FDA Guidance document "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers" issued in September 2008. The acoustic output is measured and calculated per NEMA UD 2: 2004 Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment and NEMA UD 3: 2004 Standards for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment. The device conforms to applicable medical device safety standards, such as IEC 60601-1, IEC 60601-1-1, IEC 60601-1-2, IEC 60601-2-37, IEC 60601-1-4 and ISO 10993-1.

### Conclusion:

The conclusions drawn from testing of the DC-7 Diagnostic Ultrasound System demonstrate that the device is as safe and effective as the legally marketed predicate devices.



JUN 3 - 2010

Food and Drug Administration 10903 New Hampshire Avenue Document Control Room –WO66-G609 Silver Spring, MD 20993-0002

Shenzhen Mindray Bio-Medical Electronics Co., Ltd. % Mr. Robert Mosenkis
President
CITECH
5200 Butler Pike
Plymouth Meeting, PA 19462

Re: K101041

Trade/Device Name: DC-7 Diagnostic Ultrasound Systems

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulatory Class: II

Product Code: IYN, ITX, and IYO

Dated: April 13, 2010 Received: April 14, 2010

Dear Mr. Mosenkis:

This letter corrects our substantially equivalent letter of April 30, 2010.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the DC-7 Diagnostic Ultrasound Systems, as described in your premarket notification:

### Transducer Model Number

<u>3C5A</u>				<u>7L5</u>
<u>C5-2</u>				L12-4
<u>V10-4</u>				L7-3
<u>V10-4B</u>		•		L11-4
<u>6C2</u>				L14-6
<u>7L4A</u>				2P2

<u>4CD4</u>				<u>P12-4</u>
<u>P4-2</u>				<u>7LT4</u>
<u>P7-3</u>	•	•	,	DE10-3

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21) CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Paul Hardy at (301) 796-6542.

Sincerely yours,

for: Donald St. Pierre

**Acting Director** 

Division of Radiological Devices Office of In Vitro Diagnostic Device

**Evaluation and Safety** 

Center for Devices and Radiological Health

Enclosure(s)

# Indications for Use

Stock) (Milliper (II known).	
Device Name: DC-7 Diagnostic Ultrasound System	
Indications For Use:	
The DC-7 Diagnostic Ultrasound System is applicable for adults, pregregation patients and neonates. It is intended for use in abdominal, ca (breast, testes, thyroid, etc.), peripheral vascular, fetal, transrectal, transpediatric, neonatal cephalic, musculoskeletal (conventional and superfinitraoperative and transcranial exams.	irdiac, small organ nsvaginal,
•	
Prescription Use X AND/OR Over-The-Counter (Part 21 CFR 801 Subpart D) (21 CFR 807 Subp	
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Concurrence of CDRH, Office of In Vitro Diagnostic Devices	s (OIVD)
(Division Sign-Off)  Division of Radiological Devices  Office of In Vitro Diagnostic Device Evaluation and Safety	age 1 of1
510K_K101041	

System	×			Transduc	cr	3.6				
Model:		. Ľ	C-7		_					
510(k) Number(s)					-					
								• /		
,				Mode of Operation						
Clinical Application	В	М	PWD	CMĎ	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)		
Ophthalmic										
Fctal	P	_ P	P		Ь	Р	P	Notc1,2, 3, 4,7,8		
Abdominal	Р	. Ъ	Р	Ρ.	Р	Р	P	Note1,2, 3, 4,5,7,8		
Intraoperative (specify)*	N	Ņ	N		N	N .	Ν	Note 1,2, 4,7,8		
Intraoperative (Neuro)								·		
Laparoscopic										
Pediatrie	p	P	P	P	Р	Р	P	Note 1, 2, 4,5,7,8		
Small organ(specify)**	P	þ	P		P	P	Ρ.	Note1, 2, 4,7,8		
Neonatal Cephalic	P	P	P	P	P	P	P	Note1, 2, 4,5,7,8		
Adult Cephalic	P	Р	P	Р	Р	P	P	Note1, 2, 4,5,7,8		
Trans-rectal	Р	p	P		P	P	P	Note 1,2,3,4,7,8		
Trans-vaginal	Р	Р	P		Р	P	P	Note 1,2,3,4,7,8		
Trans-urethral								, , , , , , , , , , , , , , , , , , , ,		
Trans-esoph.(non-Card.)										
Musculo-skeletal Conventional	P	P	Ρ.		Р	P	P	Note 1,2,4,7,8		
Musculo-skeletal Superficial	P	P	P		Р	P	P	Note 1,2,4,7,8		
Intravascular										
Cardiac Adult	P	P	P	P	P	P	P.	Note 1,2,5,7,8		
Cardiac Pediatric	P	P	P	Р	Р	P	P	Note 1,2,5,7,8		
Intravascu)ar (Cardiae)										
Trans-esoph.(Cardiac)										
Intra-Cardiac										
Peripheral Vascular	P	Р	P		Р	Р	Р	Note 1,2,4,7,8		
Other (specify)***										

N=new indication; P=proviously cleared by FDA; E=added under Appendix E	
Additional comments: Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + P	W +B.
*Intraoperative includes abdominal, thoracic, and vascular etc.	
**Small organ-breast, thyroid, testes, etc.	
Note 1: Tissue Hannonic Imaging. The feature does not use contrast agents.	
Note 2; Smart3D	
Note 3:4D(Real-time 3D)	
Note 4: iScape	
Note5: TDI	
Note6: Contrast Imaging	
Note7: Color M	
Note8: Biopsy Guidance	
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Concurrence of CDRH, Office of Device Evaluation(ODE)	

Prescription USE (Per 21 CFR 801.109)

System				Transdu	icer.	×					
Model:		3	C5A								
510(k) Number(s)		Ku	63041								
	Mude of Operation										
Clinical Application	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)			
Ophthalmic					4.						
Fetal	Р	P	Р		Р	P	Р	Note 1, 2, 4,7,8			
∧bdominal `	P	P	P		P	P	P	Note 1, 2, 4,7,8			
Intraoperative (specify)*											
Intraoperative (Neuro)											
Laparoscupic											
Pediatric	Р	P	Р		P	P	Р	Note 1, 2, 4,7,8			
Small organ(specify)**	1				1						
Neonatal Cephalic	1										
Adult Cephalic	<del>                                     </del>	_	1								
Trans-rectal			1					<del></del>			
Trans-vaginal			1								
Trans-urcthral	<del> </del>	<del> </del>	-	<del>                                     </del>	<del> </del>	<b></b>					
Trans-csoph.(non-Card.)	+	<del>                                     </del>	$\vdash$	$\vdash$		<del> </del>	<u> </u>				
Musculo-skeletal Conventional	P	Р	P	<del>                                     </del>	P	Р	P	Note 1, 2, 4,7,8			
Musculo-skeletal Superficial	<del> </del>	<del>                                     </del>	<del>                                     </del>		<del>                                     </del>	•	· ·	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,			
Intravascular	+	<del>                                     </del>	<del>                                     </del>	<del>                                     </del>	<del>                                     </del>	<u> </u>	<del>                                     </del>				
Cardiac Adult	+		_	<del>                                     </del>	-	<del>                                     </del>		<u> </u>			
Cardiac Pediatric	+	-	+		<del>  - :                                  </del>	<u> </u>	<del>                                     </del>	-			
Intravescular (Cardiac)	+	-	+		<del>                                     </del>	<del>                                     </del>					
Trans-esoph.(Cardiac)	1	<del>                                     </del>	1	1	<del> </del> -	<u> </u>					
Intra-Cardiac	+	<del> </del>	+	<del> </del>				<u> </u>			
Peripheral Vascular	Р	P	P		P	P	P	Note 1, 2, 4,7,8			
Other (specify)	┼∸	<del>                                      </del>	+ -	+	<del> </del> -	<del> </del>	<del>                                     </del>	11010 17 17 17 10			
N=new indication; P=previously	cleared	by ED	A · Easd	ded unde	r Annendi	. F					
Additional comments: Combined							olor+ B. Pow	er + PW +B			
*Intraoperative includ						0,1 11 101	3,01. 0,10.				
**Small organ-breast,											
Note 1: Tissue Harmo				re does	not use cor	itrași agents					
Note 2: Smart3D		<u> </u>									
Note 3:4D(Real-time :	3D)	-									
Note 4: iScape											
Note5: TDI		-				· · · ·					
Note6: Contrast Imagi	ng										
Note7: Color M											
Note8: Biopsy Guidan	ice	ر						, ,			
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Prescription USE (Per 21 CFR 801.109)

Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K101041

System				Transdu	icci	Х		
Model:			25-2					
510(k) Number(s)		E0	92691				,	
	1				100	**	<del></del>	
Clinical Application	-		T	_		Operation	0 0 1	-
Списат Аррисанов	В	М	PWD	cwb	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal .	P	P	Р		Р	Р	Р	Note 1, 2, 4,7,8
Abdominal	Р	Р	Р		P	P	Р	Note 1, 2, 4,7,8
intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric	P	Ь	Р		Р	Р	P	Note 1, 2, 4,7,8
Small organ(specify)**								
Neonatal Cephalic								
Adult Cephalic								
Trans-rectal					1			
Trans-vaginal	1							
Trans-urethral	1	-						
Trans-esoph.(non-Card.)			1				-	
Musculo-skeletal Conventional	P	P	P	<del> </del>	P	Р	P	Note 1, 2, 4,7,8
Musculo-skeletal Superficial	1			1				
Intravascular	<del>                                     </del>	†				<u> </u>		
Cardiac Adult	<del>                                     </del>	1	$\vdash$					
Cardiac Pediatric	†	<b>†</b>			1			
Intravascular (Cardiac)	<del>                                     </del>					1		
Trans-esoph.(Cardiac)	_				1			-
Intra-Cardiac	<u>†                                     </u>	1		1				
Peripheral Vascular	Р	P	P		Р	Р	P	Note 1, 2, 4,7,8
Other (specify)			1					
N≃new indication; P=previously	cleared	by FD/	4; E≂ado	led unde	r Appendi	хE		L
Additional comments:Combined							lor+ B, Pow	er + PW +B.
*Intraoperative include	es abdo	minal,	horacic,	and vas	cular etc.			
**Small organ-breast,	thyroid	testes	etc.					
Note 1: Tissue Harmon	nic Imag	ging. T	he featu	re does n	ot use cor	trast agents.		
Note 2: Smart3D								
Note 3:4D(Real-time 3	D)							
Note 4: iScape								
NoteS: TD1								
Note6: Contrast Imagin	ng					· .	· · · · ·	
Note7; Color M				<del></del>				
Note8: Biopsy Guidan		110.1.15	IE GOV	771.71.5		THE DATE		~.
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Prescription USE (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K101041

Transducer

Model:		ν	10-4								
			10-4								
510(k) Number(s)		KO	/2691					e è			
	- Mode of Operation										
Clinical Application .	В	М	PWD	CMD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)			
Ophthalmic .											
Fetal	P	Р	l,		P	Р	Р	Note 1, 2, 4,7,8			
Abdominal											
Intraoperative (specify)*											
Intraoperative (Neuro)											
Laparoscopic											
Pediatric			1								
Small organ(specify)**	1			<b> </b>							
Neonatal Cephalic	1		<u> </u>		· ·						
Adult Cephalic	1										
Trans-rectal	P	P	P		Р	P	. P	Note 1, 2, 4,7,8			
Trans-vaginal	P	P	P		P	P	Р	Note 1, 2, 4,7,8			
Trans-urethral	+	<del>                                     </del>	<u> </u>	<del>                                     </del>	<del></del>	<u> </u>	· ·	7,555 77,5			
Trans-esoph.(non-Card.)	<del> </del>	<del> </del>	<del>                                     </del>	<del> </del>	1						
Musculo-skeletal Conventional	+	╁	1	<del>                                     </del>							
Musculo-skeletal Superficial	+-		-								
Intravascular	┼	-	·	<del> </del>		<del> </del>					
Cardiac Adult	+	<del>                                     </del>	+	<del>                                     </del>		<del> </del>					
Cardiac Pediatric	<del> </del>	-	┼──	<del>                                     </del>	-			7.7.			
	+	┼	┼	-	<del> </del>						
Intravascular (Cardiac)	+		+		. 1						
Trans-esoph.(Cardiac)	<del> </del>		-	<del> </del>	<del> </del>	<del> </del>	<del> </del>				
Intra-Cardiac	+	┼	┿	-	<del> </del>			<del></del>			
Peripheral Vascular			<del> </del>	<del>                                     </del>	<del> </del>	<del> </del>	-				
Other (specify)***	<del>ا ب</del>		<u> </u>	<u> </u>	<del>!</del>	<u> </u>	<u> </u>				
N=new indication; P=previously							1 . 5 5				
Additional comments:Combined						+ B, PW +C	olor+ B, Pow	er + PW +B.			
*Intraoperative includ				, and va	cular etc.		,				
**Small organ-breast,											
**Small organ-breast,	<del></del>										
Note 1: Tissue Harmo	nic ima	iging.	ne ream	re does	not use co	ntrasi agents	•				
	20)										
Note 3:4D(Real-time Note 4: iScape	30)										
Note5: TDI											
Note6: Contrast Imag	ing	<del></del> ,				····					
Note7: Color M	6										
Note8: Biopsy Guidar	200										
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							LII NEEDE				
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Prescription USE (Per 21 CFR 80) (Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

System				Transdu	icer	х.		
Model:		VI	0-4B					
510(k) Number(s)		Ku	92691					
		-						
					Mode	of Operation		
Clinical Application	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	1							
Fetal	P	P	P		Р	Р	Р	Note 1, 2, 4,7,8
Abdominal								•
Intraopérative (specify)*								
Intraoperative (Neuro)			1					
Laparoscopic								
Pediatric								
Small organ(specify)**								
Neonatal Cephalic								
Adult Cephalic						1		
Trans-rectal	Р	Р	P		P	Р	Р	Note 1, 2, 4,7,8
Trans-vaginal	P	Р	Р		P	P	Р	Note 1, 2, 4,7,8
Trans-urethral								
Trans-esoph.(non-Card.)	_			<del>                                     </del>				-
Musculo-skeletal Conventional		-		1				
Musculo-skeletal Superficial			_					
Intravascular								
Cardiac Adult		Т				1		
Cardiac Pediatric	1	<del>                                     </del>	<u> </u>	<u> </u>	1			
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)	1							
Intra-Cardiac	1							
Peripheral Vascular								
Other (specify)***	1					·		
N=new indication; P=previously	cleared	by FD.	A; E=ad	ded und	r Append	ix É		
Additional comments:Combined			-				olar+ B, Pow	er + PW +B.
*Intraoperative includ	es abdor	minal,	thoracic	, and vas	cular etc.			
**Small organ-breast	thyroid	, testes	, etc.					
**Small organ-breast	thyroid	, testes	, etc.					
Note I: Tissue Harmo	nic Imaj	ging. T	he featu	re does	not use co	ntrast agents		
Note 2: Smart3D								
Note 3:4D(Real-time	3D)							
Note 4: iScape								
Note5: TDI								
Note6: Contrast Imag	ing .							
Note7: Calor M			<u> </u>					
Note8: Biopsy Guidar								
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Prescription USE (Per 21 CFR 801.109

(Division Sign-Uni)

Division of Radiological Devices

Office of In Vitro Diagnostic Device Evaluation and Safety

510K\_K101041

Diagno	ostic l	Ultra	sound	Indic	ations	for Use F	orm	
System				Transdu	icer	×		
Model:		(	5C2					
510(k) Number(s)		KO	92691					
	:				·			
					Mode o	of Operation		
Clinical Application	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal								
Abdominal	P	P	P		P	Р	Р	Note 1, 2, 4,7,8
Intraoperative (specify)*								
Intraoperative (Neuro)					,			
Laparoscopic								
Pediatric	P	P	Р		P	Р	Р	Note 1, 2, 4,7,8
Sinall organ(specify)**								
Neonatal Cephalic	P	P	Р		P	Р	Р	Note 1, 2, 4,7,8
Adult Cephalic	P	Р	P		P	Р	P	Note 1, 2, 4,7,8
l'rans-recta!			<del> </del>					
Trans-vaginal	1							
Trans-urethral								
Trans-esoph.(non-Card.)	1	-						
Musculo-skeletal Conventional	P	þ	-Р	<u> </u>	P	Р	P	Note 1, 2, 4,7,8
Musculo-skeletal Superficial	· P	P	P	<b>-</b>	P	P	P	Note 1, 2, 4,7,8
Intravascular	1			-		1		
Cardiac Adult	†							
Cardiac Pediatric	$\vdash$				1			
Intravascular (Cardiac)	<del>                                     </del>		<b>†</b>			<u> </u>	<del></del>	<del></del>
Trans-esoph.(Cardiac)	†							
Intra-Cardiac	+-		<del>                                     </del>	<del>                                     </del>	<u> </u>		· · ·	
Peripheral Vascular	P	Р	Р	<del> </del>	P	P	P	Note 1; 2, 4,7,8
Other (specify)	1		<del>                                     </del>			<del>                                     </del>	1	
N=new indication; P=previously	cleared	by FDA	A: E=ado	ied unde	r Append	ix E		
Additional comments: Combined a							lor+ B, Pow	er + PW +B.
*Intraoperative include						-		
**Small organ-breast,	thyroid	, testes,	etc.					
Note 1: Tissue Harmon	nic Ima	ging. T	he featu	re does n	ot use co	ntrast agents.		
Note 2; Smart3D								
Note 3:4D(Real-time 3	D)							
Note 4: iScape								
Note5: TD1			:					
Note6: Contrast Imagin	ng		•					
Note7: Color M								
Note8; Biopsy Guidan								
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Prescription USE (Per,21, CER 80)(199) (Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K.

System				114H3GHCC1				
Model:			7L4A		_			
510(k) Number(s)			K092691		_			
				٨	lode of Ope	ration		
Clinical Application	В	М	PWD	ĊMD	Color Dopples	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal .								
Abdominal	Ρ	Р	- Р		P	Р.	Ρ.	Note 1,2, 4,7,8
Intraoperative (specify)*								
Intraoperative (Neuro)					1			
Laparoscopic								
l'ediatric	р	ρ	Р		P	Р	Р	Note 1,2, 4,7,8
Small organ(specify)**	P	Р	Р		Р	Р	ь	Note 1,2, 4,7,8
Neonatal Cephalic	P	Р	Р		Р	Р	P	Note 1,2, 4,7,8
Adult Cephalic			1		<u> </u>			
Trans-rectal								
Trans-vaginal								
Trans-urethral								
Trans-csoph.(non-Card.)								•
Musculo-skeletal Conventional	Р	Р	Р		P	Р	. Б	Note 1,2, 4,7,8
Musculo-skeletal Superficial	Р	P	P		Р	P	Р	Note 1,2, 4,7,8
Intravascular					1			
Cardiac Adult				7				
Cardiac Pediatric								·
Intravascular (Cardiac)								
Trans-csoph.(Cardiac)								
Intra-Cardiac								
Peripheral Vascular	Р	P	P		Р.	Р	Р	Note 1,2, 4,7,8
Other (specify)***		$\vdash$	1		1			
N=new indication; P=previous!	y cleared	by FD/	A; E=adde	under Apper	ndix E	-	<u> </u>	
Additional comments:Combine						-Color+ B, F	ower + PW +	8.
*Intraoperative inclu				nd vascular et	c.			
**Small organ-breas								
Note 1: Tissue Harm	onic Im	aging. T	he feature	does not use o	ontrast age	nts.		
Note 2: Smart3D								
Note 3: 4D(Real-time	a 3D)			<u></u>				
Note 4: iScape								
Note5 : TDI								
Note6 : Contrast Ima Note7 : Color M	ging							
Note8 : Biopsy Guid	Ince.		·					
(PLEASE DO NOT WRITE BE		HTS LIN	IE.CONT	MUE ON AN	OTHER PA	GE IE NEE	DED)	

Prescription USE (Per 21 CFR 801.109)

Concurrence of CDRH, Office of Device Evaluation(ODE)

(Division Sign-Off)

Division of Radiological Devices

Office of In Vitro Diagnostic Device Evaluation and Safety

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System				Transducer		<u>×</u>			
Model:			7L3		_				
510(k) Number(s)			K092691						
				Mode of Operation					
Clinical Application	В	14	משק	CMD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)	
Ophthalmic									
Fetal			•						
Abdominal	P	P	P		þ	P	Ρ.	Note 1,2, 4,7,8	
Intraoperative (specify)*								-	
Intraoperative (Neuro)									
Laparoscopic			T						
Pediatric	P	P	P		P	Р	Р	Note 1,2, 4,7,8	
Small organ(specify)**	Ρ	Р	P		Į <sup>a</sup>	Р	Р	Note 1,2, 4,7,8	
Neonatal Cephalic	Р	P	Р		Ь	P	ь	Note 1,2, 4,7,8	
Adult Cephalic									
Trans-rectal									
l'rans-vaginai									
Trans-urethral									
Trans-esoph.(non-Card.)									
Musculo-skeletal Conventional	Р	Р	Р		P	Р	Р	Note 1,2, 4,7,8	
Musculo-skeletal Superficial	Р	P	Р		Р	Р	ь	Note 1,2, 4,7,8	
Intravascular									
Cardiac Adult .		_							
Cardiac Pediatric									
Intravascular (Cardiac)									
Trans-esoph.(Cardiac)									
Intra-Cardiac									
Peripheral Vascular	Р	P	P		Р	Р	Р	Note 1,2, 4,7.8	
Other (specify)***					1				
N=new indication; P=previously	y cleared	by FDA	; E=adde	d under Appen	dix E				
Additional comments:Combine						+Color+ B, f	ower + PW -	-B,	
*Intraoperative inclu				nd vascular etc					
**Small organ-breas				,					
Note 1: Tissue Harm	ionic Im	aging. If	ne teature	does not use c	onirasi age	nis.	<del></del>		
Note 2: Smart3D	- 70)								
Note 3:4D(Real-tim	e 3D)				•				
Note 4: iScape Note5: TDI	<del></del>								
Note6 : Contrast Ima	ning		-		<del></del>		<del></del>		
Note7 : Color M	Eng				····				
Note8: Biopsy Guid	ance							<del></del> -	
(PLEASE DO NOT WRITE BE		HIS LIN	E-CONT	INUE ON AN	OTHER PA	GE IF NEE	DED)		
Consumue of CDRH									

Prescription USE (Per 21 CFR 801.109)

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Office of In Vitro Diagnostic Device Evaluation and Safety

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	O							
System				Transducer		×		
Model:			L12-1		_			
510(k) Number(s)			K092691		_			
		·		N	lode of Ope			
Clinical Application	В	M	pwb	CMD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal .				,				<del></del>
Abdominal	Р	P	Р		P	p	h	Note 1,2, 4,7,8
Intrapperative (specify)*				1				
Intraoperative (Neuro)								
Laparoscopic								
Pediatric	p	P	Р		P	P	Γ	Note 1.2, 4,7,8
Small organ(specify)**	þ	Р	P		6	Р	P	Note 1,2, 4,7,8
Neonatal Cephalic	P	Р	· Р	,	P.	P	P	Note 1,2, 4,7,8
Adult Cephalic								
Trans-rectal								
Trans-vaginal								
Trans-urethral								
Trans-esoph.(non-Card.)			T		-			
Musculo-skeletal Conventional	P	Р	P		P	Р	Р	Note 1,2, 4,7,8
Musculo-skeletal Superficial	P	Р	Р		Р	P	Р	Note 1,2, 4,7,8
Intravascular								
Cardiac Adult								.,
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)								
Intra-Cardiac								
Peripheral Vascular	Р	Р	P		Р	P	Р	Note 1,2, 4,7,8
Other (specify)***								
N=new indication; P=previously								
Additional comments:Combined						Calor+ B, F	ower + PW +	-в.
*Intraoperative inclu		<u> </u>		nd vascular etc			<del></del>	
**Small organ-breas Note 1: Tissue Harm	<u> </u>			, dana ant uc				
Note 1: 11ssuc Harm	onic int	aging. I	ic icature	does not use e	Unitrast agei	113.		
Note 3:4D(Real-time	30)				<del>-</del> ;			
Mile 3: 4 Division	امده			· · · · · · · · · · · · · · · · · · ·				

Prescription USE (Per 21 CFR 801.109)

Note5: TDI Note6: Contrast Imaging Note7: Color M Note8: Biopsy Guidance

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Concurrence of CDRH, Office of Device Evaluation(ODE)

510K 101041

System				Transducer		×		
Model:			L7-3					
510(k) Number(s)		1	K092691		_			
					lode of Ope			
Clinical Application	<u></u>	r	<del></del> -i		Color	Amplitude	Combined	
	B	. M	OW9	CMD	Doppler	,	(specify)	Other (specify)
Ophthalmic								
Feial								
Abdominal	Р.	P	Р		P	Р	Р	Note 1,2, 4,7,8
Intraoperative (specify)*								
Intraoperative (Neuro)					,			
Laparoscopic					1			
Pediatric	P	Р	Р		P	ľ	. р	Note 1,2, 4,7,8
Small organ(specify)**	P	P	P.		P	P	Р	Note 1,2, 4,7,8
Neonatal Cephalic	Р	р	Р		P	p	P	Note 1,2, 4,7,8
Adult Cephalic								
Frans-rectal								
Frans-vaginal								
Trans-urcthral							-	
Trans-esoph.(non-Card.)				1	-			
Musculo-skeletal Conventional	Р	P	Р		Р	P	Р	Note 1,2, 4,7,8
Musculo-skeletal Superficial	Р	Р	Р		P	P	Р	Note 1,2, 4,7,8
Intravascular								
Cardine Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph.(Cardiae)								
Intra-Cardiac								
Peripheral Vascular	Р	р.	Р		Р	Р	Р	Note 1,2, 4,7,8
Other (specify)***								
N=new indication; P=previous	y cleared	by FDA	; E=added	under Appen	dix É			
Additional comments:Combine						+Color+ B, P	ower + PW +	В.
*Intraoperative inclu	THE CO. P. LEWIS CO.			id vascular etc				
**Small organ-breas				4				
Note 1: Tissue Harr	ionic ima	iging, in	c tenture (	does not use c	ontrasi agei	nts,		· · · · · · · · · · · · · · · · · · ·
Note 3:4D(Real-tim	e 3D)			· —				
Note 4: iScape	C 30)							
Note5: TDI		-						
Note6 : Contrast Ima	ging							<del></del>
Note7 : Color M								
Note8 : Biopsy Guid	ance							
(PLEASE DO NOT WRITE BE	LOW T	HIS LIN	E-CONTI	NUE ON AN	OTHER PA	GE IF NEE	DED)	
Concurrence of CDRH,	Office (	of Devi	ce Eval	ation(ODI	E)			

Prescription USE (Per 21 CFR 801.109)

System				(Tallscuce)		<u> </u>		
Model:			LII-4		_			
510(k) Number(s)			K092604		_			•
				<b>1.</b>	lode of Ope	acution .		
Clinical Application				<u></u>	Color	Amplitude	Combined	
	В	М	PWD	CWD	Doppler	Doppler	(specify)	Other (specify)
Ophthalmic					1			
Feial								
Abdominal	P	P	Р		P	Р	Р	Note 1,2, 4,7,8
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric	P	Р	ρ,		P	Р	Р	Note 1,2, 4,7,8
Small organ(specify)**	þ	, Р	P		P	Р	Р	Note 1,2, 4,7,8
Neonatal Cephalic	P	P	P		P	P	P	Note 1,2, 4,7,8
Adult Cephalic								
Trans-rectal				1				
Trans-vaginal								
Trans-urethral	-							
Trans-esoph.(non-Card.)			-					
Musculo-skeletal Conventional	P	Р	P		Р	P.	Р	Note 1,2, 4,7,8
Musculo-skeletal Superficial	P	Р	P		P	Р	Р	Note 1,2, 4,7,8
Intravascular								
Cardiac Adult ,				1				
Cardiac Pediatrie								•
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)								
Intra-Cardiac								
Peripheral Vascular	P	Р	Р		P	P.	Р	Note 1,2, 4,7,8
Other (specify)***								
N=new indication; P=previous!								
Additional comments:Combine						+Color+ B. F	ower + PW -	•В.
*Intraoperative inclu				ing vascular ele	;,		· · · · ·	
**Small organ-breas				daes eet		-10		
Note 2: Smart3D	ionic im	aging. 1	ne tentute	does not use c	Ontrast age	ms.	<del></del>	,
Note 3: 4D(Real-tim	e 3D)							
Note 4: iScape	0 3037							
Note5 : TDI								
Note6: Contrast Ima	ging							· · ·
Note7: Color M								
Note8 : Biopsy Guid	ance							
(PLEASE DO NOT WRITE BE	LOW T	HIS LIN	E-CONT	INUE ON AN	OTHER P	GE IF NEE	DED)	
Concurrence of CDRH,	Office	of Dev	ice Eval	luation(OD)	E)			

Prescription USE (Per 21 CFR 801.109)

System				Transducer		×		
Model:			1.14-6		_			
510(k) Number(s)			Kua5091		_			
		,	·	٨.	lode of Op			
Clinical Application	В	м	rwb	CWD	Color Dappler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalinic								
Feial								
Abdominal	Р	P	ь		P	P	Р	Note 1,2, 4,7,8
Intraoperative (specify)*								
Intraoperative (Neuro)								
1_aparoscopic								
Pediatric	P	Р	Р		Р	Р	Р	Note 1,2, 4,7,8
Small organ(specify)**	Р	P	P		Р	P	Р	Note 1,2, 4,7,8
Neonatal Cophalic	Р	Р	P		Р	P	Р	Note 1,2, 4,7,8
Adult Cephalic								
Trans-rectal								·
Trans-vaginal		1						
Trans-urethral								
Trans-esoph.(non-Card.)								
Musculo-skeletal Conventional	Р	۲	P		Р	P	P	Note 1,2, 4,7,8
Musculo-skeletal Superficial	P	P	Р		Р	Р	P	Note 1,2, 4,7,8
Intravascular								
Cardiac Adult					ì			
Cardine Pediatric								
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)								
intra-Cardiac								
Peripheral Vascular	P	P	Р		P	Р	P	Note 1,2, 4,7,8
Other (specify)***				•				
N=new indication; P=previousl								
Additional comments:Combine						+Color+ B, F	ower + PW	<del>+</del> B.
*Intraoperative inch				nd vascular et	<del>}.</del>		<del></del>	
**Small organ-breas				4			<del></del>	
Note 1: Tissue Harm	ionic im	aging. (	ne teature	does not use o	ontrast age	nts.		<del></del>
Note 3:4D(Real-tim	- 30)						<u>.</u>	
Note 4: iScape	£ 30)						~	
Note5: TDI				***			p	
Note6: Contrast Ima	aging				<del></del>			
Note7: Color M	-9···0							
Note8 : Biopsy Guid	ance						<del></del>	
(PLEASE DO NOT WRITE BE		HIS LIN	E-CONT	INUE ON AN	OTHER P	AGE IF NEE	DED)	

Prescription USE (Per 21 CFR 801.109)

Concurrence of CDRH, Office of Device Evaluation(ODE)

System				Transdu	cer	×		
Model:			2P2		_			
510(k) Number(s)		K0	92691					
<u> </u>	ī					du of Onoro	· · · · · · · · · · · · · · · · · · ·	
Clinical Application			Low			de of Operat	,	
Cilinear Application	В	М	PW D	CWD	Cotor Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal							·	
Abdominal	Р	Ъ	P	P	P	P	P	Note 1, 2,5,7,8
Intraoperative (specify)*								
Intraoperative (Neuro)	$\Box$		П					
Laparoscopic	$\sqcap$							
Pediatric	Р	·P	P	Р	Р	Р	ľ	Note 1, 2,5,7,8
Small organ(specify)**								
Neonatal Cephalic	Р	P	P	P	Р	P	Р	Note 1, 2,5,7,8
Adult Cephalic	Р	Р	P	P	Р	P	P	Note 1, 2,5,7,8
Trans-rectal			$\Box$					
Trans-vaginal								
Trans-urethral								
Trans-esoph.(non-Card.)								'
Musculo-skeletal Conventional	1							
Musculo-skeletal Superficial						1		
Intravascular	$\top$							
Cardiac Adult	þ	Р	P	Р	Р	Р	Р.	Note 1, 2,5,7,8
Cardiac Pediatric	Р	P	P	Р	P	Р	Р	Note 1, 2,5,7,8
Intravascular (Cardiac)			$\top$					
Trans-esoph.(Cardiac)								
Intra-Cardiac			1				1	
Peripheral Vascular					1			
Other (specify)***							1	
N=new indication; P=previously	cleared	by FI	DA; E	added u	nder Appe	ndix E		
Additional comments:Combined	modes:	В+М	, PW+	B, Color	+ B, Pow	er + B, PW +	-Color+ B, Po	wer + PW +B.
*Intraoperative includ	es abdo	mina	, thor	cic, and	vascular c	Ic.		
**Small organ-breast,	thyroid	i, test	es, etc.					
Note 1: Tissue Harmo	nic Ima	ging.	The fe	ature do	es not use	contrast age	nts.	
Note 2: Smart3D								
Note 3: 4D(Real-time	3D)							· · · · · · · · · · · · · · · · · · ·
Note 4: iScape								
Note5: TDI								<del> · · · · · · · · · · · · · · · · · ·</del>
Note6: Contrast Imag	ing							
Note7: Color M								

Prescription USE (Per 21 CFR 801.109)

Note8: Biopsy Guidance

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Concurrence of CDRH, Office of Device Evaluation(ODE)

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System				rionsau								
Model:			CD4	<u> </u>	-		•					
510(k) Number(s)	K10/2641											
	Mode of Operation											
Clinical Application	В	М	PW	CWD	Color •Doppler	Amplitude Doppler		Other (specify	()			
Ophthalmic						,						
Fetal	P	P	Р		P	Р	Р	Note1,2, 3, 4	,7			
Abdominal	P	Р	P		P	P	P	Note 1,2, 3, 4	,7			
Intraoperative (specify)*												
Intraoperative (Neuro)	1.											
Laparoscopic												
Pediatric	P	P	P		P	Р	P	Note1,2,4,	7			
Small organ(specify)**												
Neonatal Cephalic												
Adult Cephalic	1			<del> </del>	1							
Trans-rectal	+		1									
Trans-vaginal	$\vdash$		t			<del></del>						
Trans-urethral	1-	-	1	<b></b>	<del>                                     </del>							
Trans-esoph.(non-Card.)	†	-	<del> </del>		<u> </u>							
Musculo-skeletal Conventional	+-	$\vdash$	<del>                                     </del>	$\vdash$	<del>                                     </del>							
Musculo-skeletal Superficial	+	$\vdash$	<del>                                     </del>		<del>†                                      </del>	<del> </del>						
Intravascular	+	-	+				-					
Cardiac Adult	+-	_	<del> </del>	-	1							
Cardiac Pediatric	+		-	-	<del>                                     </del>	<u> </u>						
Intravascular (Cardiac)	+	-	1		+	<del> </del>	<del>  </del>	· · · · · · · · · · · · · · · · · · ·	-			
Trans-esoph.(Cardiac)	+	-	$\vdash$	<del>                                     </del>	<del> </del>				-			
Intra-Cardiac	+	-	+-	<del> </del>	+	<del>                                     </del>		<del></del>				
Peripheral Vascular	+-	<del>                                     </del>		-	+	-						
Other (specify)***	┼─	-	┼		1	ļ.——	-					
N=new indication; P=previously	cleared	by El	34 · F=	added u	nder Appe	ndiv E	<u>!</u>					
Additional comments:Combined							Color+ B. Po	wer + PW +R				
*Intraoperative includ							Color B, ru	wet 11 W 7D.				
**Small organ-breast,							· · · · · · · · · · · · · · · · · · ·		<del></del>			
Note 1: Tissue Harmo					es not use	Contrast ages	115.					
Note 2: Smart3D		55										
Note 3: 4D(Real-time	3D)											
Note 4: iScape				,								
Note5: TDI			*									
Note6 : Contrast Imag	ing											
Note7: Color M												
Note8 : Biopsy Guidar	ice											
(PLEASE DO NOT WRITE BEL	OW TI	HIS L	INE-C	ONTIN	UE ON AN	OTHER PA	GE IF NEED	ED)				
Concurrence of CDRH, C	ffice	of D	evice	Evalu	ation(Ol	DE)						
Prescription USE (Per 21 CF  Comparison of the C	Nvision of Radi	Sign	-Off)	vices luation s	and Safety	,						
610K	010	24	/						1			

System				Transdu	cer	×			
Model:		1	4-2		_			•	
510(k) Number(s)					-				
						·			
					Мо	de of Operat	ion		
Clinical Application	8	М	PW D	CWD	Color Dappler	Amplitude Doppler	Combined (specify)	Other (specify)	
Ophthalmic									
Fetal				,					
Abdominal	N	Ν	N	N	N	N	N	Note 1, 2,5,7,8	
Intraoperative (specify)*									
Intraoperative (Neuro)									
Laparoscopic								The state of the s	
Pediatric	N	N	N	N	N	N	N	Note 1, 2,5,7,8	
Small organ(specify)**	$\Box$								
Neonatal Cephalic	N	N	N	N	N	N	N ·	Note 1, 2,5,7,8	
Adult Cephalic	N	N	N	N	N	N	N	Note 1, 2,5,7,8	
Trans-rectal									
Trans-veginal									
Trans-urethral								•	
Trans-csoph.(non-Card.)									
Musculo-skeletal Conventional									
Musculo-skeletal Superficial	$\vdash$				Ť.				
Intravascular									
Cardiac Adult	N	N	N	N	N	N	N	Note 1, 2,5,7,8	
Cardiác Pediatric	N	N	N	· N	N	N	N	Note 1, 2,5,7,8	
Intravascular (Cardiac)									
Trans-esoph.(Cardiac)	$\top$								
Intra-Cardiac	1			-					
Peripheral Vascular									
Other (specify)***									
N=new indication; P=previously	cleared	by FC	A; E	added ur	ider Appei	ndix E			
Additional comments:Combined	modes:	в+м.	PW+	B, Calor	+ B. Powe	r + B, PW +	Color+ B, Po	wer + PW +B.	
*Intraoperative includ	es abdo	minal,	thora	cic, and v	ascular et	c,			
**Small organ-breast,	thyroid	, teste	s, cic.						
Note 1: Tissuc Harmo	nic Ima	ging.	The fe	ature doe	s not use o	contrast agen	ts.		
Note 2: Smart3D									
Note 3:4D(Real-time	3D)								
Note 4: iScape						•			
Note5: TDI									
Note6: Contrast Imagi	imaging								
Note7: Color M									
Note8: Biopsy Guidan		J10 1 1	NG-C	ONTING	IE ON AN	OTUED DA	CE IE NECO	CD)	
Concurrence of CDRH, O							GE IF NEED	ED)	
Concurrence of CDRI, U	THE C	טו ויי	TICC	DAMINA	mon(OL	زناد			

Prescription USE (Per 21 CFR 801.109)

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System				Transdu	cer	×		
Model:		ſ	7-3					
510(k) Number(s)								
	Ī			·	Mo	de of Opera	tion	
Clinical Application	В	М	PW D	CWD	Calar Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal .								
Abdominal	N	Ν	N	N	N	N ·	N	Note 1, 2,5,7
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic	1					<b></b>		
Pediatric	N	N	N	N	N	N	N	Note 1, 2,5,7
Small organ(specify)**	1		$\vdash$					
Neonatal Cephalic	N	N	N	N	N	N	N	Note 1, 2,5,7
Adult Cephalic	N	N	N	N	N	N	N	Note 1, 2,5,7
Trans-rectal	<del>                                     </del>	<u> </u>	1		<del>                                     </del>	<del>                                     </del>	<del></del>	
Trans-vaginal	$\vdash$		<del> </del>	<del> </del>	· · · · ·	<del> </del>	<del>                                     </del>	
Trans-urethral	$\vdash$	_	<u> </u>		<del>                                     </del>	<del> </del>		
Trans-esoph.(non-Card.)	$\vdash$				<del>                                     </del>			
Musculo-skeletal Conventional	N	N	N	<u> </u>	N	N.	N	Note 1, 2,7
Musculo-skeletal Superficial	<del>                                     </del>		<del>                                     </del>	<del>                                     </del>		<u> </u>	- ' '	11010 1, 2,7
Intravascular	$\vdash$		<del>                                     </del>		<del>                                     </del>			
Cardiac Adult	N	N	N	N.	N	N	N	Note 1, 2,5,7
Cardiac Pediatric	N	N	N	N	N	N	N	Note 1, 2,5,7
Intravascular (Cardiac)	<del>                                     </del>				1			
Trans-esoph (Cardiac)	$\vdash$		$\vdash$		<del> </del>		l	
Intra-Cardiac	$\vdash$				† <b>-</b>			
Peripheral Vascular	<del>                                     </del>	-						-
Other (specify)***	1	-	-			<del> </del>		
N=new indication; P=previously	cleared	by Ff	)A· E	added n	nder Anne	ndiv E		
Additional comments:Combined							+Color+ B. Po	wer + PW +R
*Intraoperative includ								
**Small organ-breast,					14554141.5			
Note 1: Tissue Harmo					es not use	contrast age	nis.	
Note 2: Smart3D				-				
Note 3:4D(Real-time 3	(D)					·	<del></del>	
Note 4: iScape								
Note5: TD1					Ŧ			
Note6: Contrast Imagi	ng						***************************************	
Note7: Color M								
Note8: Biopsy Guidan	ce							
(PLEASE DO NOT WRITE BEL	OW T	HIS L	INE-C	ONTIN	UE ON A	NOTHER PA	GE IF NEED	ED)
Concurrence of CDRH, O	ffice	of De	evice	Evalua	ation(Ol	DE)		

Prescription USE (Per 2) EFR 101 948

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Office of In Vitro Diagnostic Device Evaluation and Safety

Diagi	watic	Ott	1 41.70	and th	arcano	11.3 101 03		
System				Transdu	cer ·	×		
Model:		P	12-4					T.
510(k) Number(s)							,	
	<u>.</u>			1	Мо	de of Operat	ion	
Clinical Application	В	М	PW D	ćwo	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal								
Abdominal	Ŋ	N	N	N	N	N	N	Note 1, 2,5,7
Intraoperative (specify)*								
Intraoperative (Neuro)			Ī					
Laparoscopic								
Pediatric	N·	N	N	N	N	N	N	Note 1, 2,5,7
Small organ(specify)**								
Neonatal Cephalic	N	N	N	N	N	N	·N	Note 1, 2,5,7
Adult Cephalic	N	N	N	N	N	N	N	Note 1, 2,5,7
Trans-rectal								
Trans-vaginal								
Trans-urethral								
frans-esoph (non-Card.)								
Musculo-skeletal Conventional	N	N	N		N	N	N	Note 1, 2,7
Musculo-skeletal Superficial								1
Intravascular	1							
Cardiac Adult	N	N	N	N	N	N	И.	Note 1, 2,5,7
Cardiac Pediatric	N	N	N	N	N	N	N	Note 1, 2,5,7
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)					1			
Intra-Cardinc								
Peripheral Vascular			Π					,
Other (specify)***								
N=new indication; P=previously	cleared	by FI	DA; E	=added u	inder Appo	endix E		,
Additional comments:Combined	modes:	В+М	, PW-	B, Color	+ B, Pow	er + B, PW -	+Color+ B, Po	ower + PW +B.
*Intraoperative includ	es abdo	mina	t, thor	acic, and	vascular c	lc.		
**Small organ-breast,	thyroid	d, test	es, etc					
Note 1: Tissue Harmo	nic Ima	ging.	The f	eature do	es not use	contrast age	nts.	•
Note 2: Smart3D								
Note 3:4D(Real-time	3D)					•		
Note 4: iScape								
Note5: TDI								

Prescription USE (Per 21 CFR 801.109)

Note6: Contrast Imaging Note7: Color M Note8: Biopsy Guidance

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Concurrence of CDRH, Office of Device Evaluation(ODE)

System				Transduce	r	×		
Model:		7	LT4					
510(k) Number(s)								
•								
					Mode of C	peration		
Clinical Application	В	М	PWD	CWD	Color Doppier	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal								
Abdominal	N	N	N		N	N	N	Noie 1,2, 4,7,8
Intraoperative (specify)*	N	N	N		N	N	N	Noic 1,2, 4,7,8
Intraoperative (Neuro)								
Laparoscopic								
Pediatric	N	N	N		N	N	N	Note 1,2, 4,7,8
Small organ(specify)**	N	N	N		N	N	N	Note 1,2, 4,7,8
Neonatal Cephalic	N	N	N		N	N	И	Note 1,2, 4,7,8
Adult Cephalic								
Trans-rectal								
Trans-vaginal				-				
Trans-urethral								
Trans-esoph.(non-Card.)								
Musculo-skeletal Conventional	N	N	N		N	N	N	Note 1,2, 4,7,8
Musculo-skeletal Superficial	N	N	N		N	N	N	Note 1,2, 4,7,8
Intravascular								
Cardiac Adult				<del>                                     </del>				
Cardiac Pediatric								
Intravascular (Cardiac)			<u> </u>		· · · · ·			· · · · · · · · · · · · · · · · · · ·
Trans-esoph.(Cardiac)		,				1		
Intra-Cardiac						<b></b>		
Peripheral Vascular	N	N	N		N	N	N	Note 1,2, 4,7,8
Other (specify)***						<del></del>		
N=new indication; P=previously	cleared	by FDA	: E=adde	d under Ap	pendix E			
Additional comments: Combined	i modes:	B+M, P	W+B, Co	lor + B, Pa	wer + B, I	PW +Color+	B, Power +	PW +B.
· *Intraoperative inclu	des abde	ominal, t	horacic, p	nd vascular	retc.			
**Small organ-breas								
Note 1: Tissue Harm	onic Im	aging. Th	e feature	does not u	se contrasi	agents.		
Note 2: Smart3D								
Note 3:4D(Real-time	3D)			·				
Note 4: iScape								
Note5: TD1	-1							
Note6: Contrast Imag	ging							· · · · · · · · · · · · · · · · · · ·
Note7: Color M Note8: Biopsy Guida	nce			•				
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Concurrence of CDRH.								

Prescription USE (Per 21 CFR 801.109)

System				Transdu	icer	×		
Model:		DE	10-3					
510(k) Number(s)						4		
					,			
					Mode	of Operation		
Clinical Application	В	М	טשיו	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal .	N	7	N		N	И	N	Note 1, 2,3, 4,7
Abdominal				<u> </u>				
Intraoperative (specify)*								
Intraoperative (Neuro)								<u> </u>
Laparoscopic								
Pediatric '	1							
Small organ(specify)**			Ī .					
Neonatal Cephalic								•
Adult Cephalic								
Trans-rectal	N	N	N		N	7	N	Note 1, 2, 3,4,7
Trans-vaginat	N	N	N		N	N	N	Note 1, 2, 3,4,7
Trans-urethral					Ī			
Trans-esoph.(non-Card.)				. '				
Musculo-skeletal Conventional								
Musculo-skeletal Superficial								
Intravascular	T							
Cardiac Adult	$T_{L}$							
Cardiac Pediatric					l			
Intravascular (Cardiac)	Ţ							
Trans-esoph (Cardiac)			<u> </u>		ľ.			
Intra-Cardiac								
Peripheral Vascular								
Other (specify)***			<u> </u>		<u> </u>	<u> </u>		
N=new indication; P=previously								
Additional comments:Combined							olor+ B, Pov	/er + PW +B.
*Intraoperative include		_		, and va	scular etc.			
**Small organ-breast								
**Small organ-breast				4				<del></del>
Note 1: Tissue Harmo	onic Ime	aging.	the teat	ure does	not use co	ntrast agent	s. ·	
Note 2: Smart3D Note 3:4D(Real-time	30\		<del></del>					
Note 4: iScape	30)					···	· · · · · · · · · · · · · · · · · · ·	
Note5: TDI								
Note6: Contrast Imag	ing							
Note7: Color M								
Note8: Biopsy Guida	nce							
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Concurrence of CDRH,				_				
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